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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/185,908	11/03/98	BLASCHUK	0 1000086.49

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EXAMINER

DECLoux, A

ART UNIT	PAPER NUMBER
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1644

*21*

DATE MAILED: 10/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/185,908

Applicant(s)

Blaschuck et al

Examiner

DeCloux, Amy

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 24, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-63 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 2-63 are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

#### DETAILED ACTION

1. The request filed 8-24-01 (Paper No. 18) for a continued Prosecution Application (CPA) under 37 CFR 1.53.(d) based on parent application No. 09/ 185,908 is acceptable and a CPA has been established. An action on the CPA follows.
2. Applicant's amendment, filed 8-24-01 (Paper No. 19), is acknowledged and has been entered.
3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 2-6, 27-32 and 35-37, drawn to a cell adhesion modulating agent comprising a linear Claudin CAR sequence, and a pharmaceutical composition thereof, classified in Class 530, subclass 300, and Class 514, subclasses 12-17,
  - II. Claims 2-4, 7-20, 27-32 and 35-37, drawn to a cell adhesion modulating agent comprising a cyclic CAR sequence, and a pharmaceutical composition thereof, classified in Class 530, subclass 317, and Class 514, subclass 9,
  - III. Claims 2-4 and 21-23, drawn to a polynucleotide, vector and host cell, classified in Class 435, subclasses 320.1 and 325, and class 536, subclass 23.1,
  - IV. Claim 24, drawn to a modulating agent comprising an antibody directed to a claudin CAR sequence of SEQ ID NO:1, classified in Class 530, subclasses 387.1 and 387.9,
  - V. Claims 25-26, drawn to a modulating agent comprising a mimetic of claudin CAR sequence, classified in Class 530, subclass 300,
  - VI. Claims 2-4, 33(a) and 34, drawn to a cell adhesion modulating agent comprising a Claudin CAR sequence and further comprising a CAR sequence that is bound by an adhesion molecule other than claudin, classified in Class 530, subclass 300, and Class 514, subclasses 12-17,
  - VII. Claims 2-4, 33(b) and 34, drawn to a cell adhesion modulating agent comprising a Claudin CAR sequence and further comprising an antibody that binds a cell adhesion recognition sequence bound by an adhesion molecule other than a claudin, classified in Class 530, subclasses 300, 387.1 and 387.9, and Class 514, subclasses 12-17,
  - VIII. Claims 2-4, 35, 38(a) and 39, drawn to a pharmaceutical composition comprising a cell adhesion modulating agent, further comprising a peptide that comprises a CAR sequence that is bound by an adhesion molecule other than a claudin, classified in Class 530, subclass 300, and Class 514, subclasses 12-17,
  - IX. Claims 2-4, 35, 38(b) and 39, drawn to a pharmaceutical composition comprising a cell adhesion modulating agent, further comprising an antibody to a CAR

sequence bound by an adhesion molecule other than a claudin molecule, classified in Class 530, subclasses 300, 387.1 and 387.9, and Class 514, subclasses 12-17, and Class 530, and class 424, subclass 130.1,

X. Claims 2-4 and 40-41, drawn to a claudin modulating agent comprising one or more of a linear claudin -1 sequence classified in Class 530, subclass 300,

XI. Claims 2-4 and 40, 42-43, drawn to a claudin modulating agent comprising one or more of a cyclic claudin -1 sequence, classified in Class 530, subclass 317,

XII. Claims 2-4, 40-41 and 44, drawn to a polynucleotide encoding one or more of a linear claudin -1 sequence, classified in class 536, subclass 23.1,

XIII. Claims 2-4 and 40, 42-44, drawn to a polynucleotide encoding one or more of a cyclic claudin -1 sequence, classified in class 536, subclass 23.1,

XIV. Claim 45, drawn to an antibody to the claudin-1 CAR sequence SEQ ID NO:34, classified in Class 530, subclasses 387.1 and 387.9,

XV. Claims 2-4 and 46-47, drawn to a claudin modulating agent comprising one or more of a linear claudin-2 CAR sequence, classified in Class 530, subclass 300,

XVI. Claims 2-4, 46 and 48-49, drawn to a claudin modulating agent comprising one or more of a cyclic claudin-2 CAR sequence, classified in Class 530, subclass 317,

XVII. Claims 2-4, 46-47 and 50, drawn to a polynucleotide encoding one or more of a linear claudin-2 CAR sequence, classified in class 536, subclass 23.1,

XVIII. Claims 2-4, 46 and 48-50, drawn to a polynucleotide encoding one or more of a cyclic claudin-2 CAR sequence, classified in class 536, subclass 23.1,

XIX. Claim 51, drawn to an antibody to the claudin CAR-2 sequence of SEQ ID NO:42, classified in Class 530, subclasses 387.1 and 387.9,

XX. Claims 2-4 and 52-53, drawn to a claudin modulating agent comprising one or more of a linear CPE-R CAR sequence, classified in Class 530, subclass 300,

XXI. Claims 2-4, 52 and 54-55, drawn to a claudin modulating agent comprising one or more of a cyclic CPE-R CAR sequence, classified in Class 530, subclass 317,

XXII. Claims 2-4, 52-53 and 56, drawn to a polynucleotide encoding one or more of a linear CPE-R CAR sequence, classified in class 536, subclass 23.1,

XXIII. Claims 2-4, 52 and 54-56, drawn to a polynucleotide encoding one or more of a cyclic CPE-R CAR sequence, classified in class 536, subclass 23.1,

XXIV. Claim 57, drawn to an antibody to CPE-R CAR sequence of SEQ ID NO:58, classified in Class 530, subclasses 387.1 and 387.9,

XXV. Claims 2-4 and 58-59, drawn to a claudin modulating agent comprising one or more of a linear RVP-1 CAR sequence, classified in Class 530, subclass 300,

XXVI. Claims 2-4, 58 and 60-61, drawn to a claudin modulating agent comprising one or more of a cyclic RVP-1 CAR sequence, classified in Class 530, subclass 317,

XXVII. Claims 2-4, 58-59 and 62, drawn to a polynucleotide encoding one or more of a linear RVP-1 CAR sequence, classified in class 536, subclass 23.1,

XXVIII. Claims 2-4, 58 and 60-62, drawn to a polynucleotide encoding one or more of a cyclic RVP-1 CAR sequence, classified in class 536, subclass 23.1,

XXIX. Claim 63, drawn to an antibody to RVP-1 CAR sequence of SEQ ID NO:58, classified in Class 530, subclasses 387.1 and 387.9,

Note each claim will be examined only to the extent of the elected invention.

4. Inventions I-XXIX are different products. They differ with respect to their physicochemical properties and are therefore patentably distinct.

5. Because Inventions I-XXIX are distinct for the reasons given above, and they have acquired a separate status in the art because the searches of the non-patent literature are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

6. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121:

4. If Groups I-III is elected, the applicant is further required under 35 U.S.C. 121,
- A) To elect a **specific number of consecutive amino acid residues of CAR sequences**, such as 5, 7 or 8 as recited in claims 2a, 3a and 4a, respectively,
  - B) To elect a **peptide of a specific number of amino acid residues**,
  - C) To elect a **specific SEQ ID NO**, wherein each residue is identified by a single amino acid, such as one of the claudin-1 CAR sequences recited in claim 5 or 6.
5. If Group II is elected, the applicant is further required,
- A) To elect a **specific tetrapeptide for "W"** as recited in claim 8,
  - B) To elect a **specific number and identity of residues for each of  $x_1$ ,  $x_2$ ,  $z_1$  and  $z_2$** , as recited in claim 8,
  - C) To elect a **specific identity of an amino acid residues for each of  $Y_1$  and  $Y_2$** , such as recited in claim 12,
  - D) To elect a **specifically how  $Y_1$  and  $Y_2$  are covalently linked**, such as recited in claims 11, 14, and 19,
- Furthermore, if amide bond is selected in part D just above, then applicant is further required to elect **the specific groups bonded**, such as recited in claims 15-17,

E) To elect a **specific SEQ ID NO**, such as one of the claudin-1 CAR sequences recited in claim 5 or 6.

6. If Group IV is elected, the applicant is further required to elect a **specific sequence** that is comprised by SEQ ID NO:1, as recited in claim 24.

7. If Group V is elected, the applicant is further required

A) To elect a **specific number of consecutive amino acid residues of CAR sequences**, such as 3 or 5, as recited in claims 25 and 26, respectively,

B) to elect a **specific sequence** that is comprised by SEQ ID NO:1, as recited in claim 25,

8. If Group VI or VII is elected, the applicant is further required

A) to elect from each of the species listed in the species election requirements of invention I,

B) to elect a **specific non- claudin cell adhesion modulating agent** such as one recited in claim 34,

9. If Group VIII or IX is elected, the applicant is further required

A) to elect from each of the species listed in the species election requirements of invention I,

B) to elect a **specific non- claudin cell adhesion modulating agent** such as one recited in claim 39.

10. If group X or XII is elected, the applicant is further required

A) to elect from each of the species listed in the species election requirements of invention I

B) to elect a **specific sequence**, such as one recited in claim 40,

C) to elect a **specific number of claudin-1 CAR sequences**,

11. If group XI or XIII is elected, the applicant is further required

A) to elect from each of the species listed in the species election requirements of invention I

B) to elect a **specific sequence**, such as one recited in claim 43,

C) to elect a **specific number of claudin-1 CAR sequences**,

12. If group XV or XVII is elected, the applicant is further required

A) to elect from each of the species listed in the species election requirements of invention I

B) to elect a **specific sequence**, such as one recited in claim 46,

- C) to elect a **specific number of claudin-2 CAR sequences**,
13. If group XVI or XVIII is elected, the applicant is further required
- A) to elect from each of the species listed in the species election requirements of invention I
  - B) to elect a **specific sequence**, such as one recited in claim 49,
  - C) to elect a **specific number of claudin-2 CAR sequences**,
14. If group XX or XXII is elected, the applicant is further required
- A) to elect from each of the species listed in the species election requirements of invention I
  - B) to elect a **specific sequence**, such as one recited in claim 52,
  - C) to elect a **specific number of CPE-R CAR sequences**,
15. If group XXI or XXIII is elected, the applicant is further required
- A) to elect from each of the species listed in the species election requirements of invention I
  - B) to elect a **specific sequence**, such as one recited in claim 55,
  - C) to elect a **specific number of CPE-R CAR sequences**,
16. If group XXV or XXVII is elected, the applicant is further required
- A) to elect from each of the species listed in the species election requirements of invention I
  - B) to elect a **specific sequence**, such as one recited in claim 58,
  - C) to elect a **specific number of RVP-1 CAR sequences**,
17. If group XXVI or XXVIII is elected, the applicant is further required
- A) to elect from each of the species listed in the species election requirements of invention I
  - B) to elect a **specific sequence**, such as one recited in claim 61,
  - C) to elect a **specific number of RVP-1 CAR sequences**,
18. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
19. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the

elected species. MPEP § 809.02(a).

20. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

21. The following claim(s) are generic: claims 2-7, 27-30, 33 and 35.

22. The species are distinct each from the other because they are different products. They differ with respect to their physicochemical properties and are therefore patentably distinct.

23. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

24. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

25. A telephone call to request an oral election was not made due to the complexity of the restriction.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax

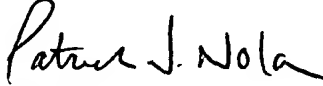


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number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

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